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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,366	03/18/2004	Frederic Triebel	1057-04	7996

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IP GROUP OF DLA PIPER US LLP
ONE LIBERTY PLACE
1650 MARKET ST, SUITE 4900
PHILADELPHIA, PA 19103

EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	**PAPER NUMBER**
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/803,366	TRIEBEL, FREDERIC	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *7-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20040318*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation of U.S. Application Serial Number PCT/IB02/04240. Claims 1-30 are currently pending.

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 5 and 6, in the reply filed on February 16, 2007 is acknowledged. The traversal is on the ground(s) that it would not constitute an undue burden on the Examiner to search Groups III and IV with Group I because they cover compositions comprising the molecules of Group I. This is not found persuasive because the inventions of groups III and IV are drawn to LAP agonists and antagonists, respectively. Group I is drawn to LAP itself. Accordingly, the groups are not drawn to the same compound as asserted by Applicant.

The requirement is still deemed proper and is therefore made FINAL.

2. **Claims 7-30 are withdrawn** from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 16, 2007.

Claims 1-4 are linking claims that will be examined with the invention of Group I.

Accordingly, **claims 1-6 are the subject of examination** in the present Office Action.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the EPO on September 19, 2001. It is noted, however, that applicant has not filed a certified copy of the EPO application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a LAP polypeptide comprising SEQ ID NO: 1 or 2 or a LAP polypeptide comprising a fragment thereof, does not reasonably provide enablement for homologs or derivatives thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claims are broadly drawn to polypeptides inclusive of homologs, fragments or derivatives of a LAP polypeptide comprising SEQ ID NO: 1 or 2.

The specification does not provide sufficient guidance to enable the full scope of peptides encompassed by the term. The term "derivative" is an open term readily understood in the art to encompass peptide whose sequence is based upon the wild-type sequence of a particular protein or peptide, but may include various additions, deletions and/or substitutions to that sequence that may or may not affect the function of the peptide as compared to the wild-type sequence. The specification does not provide any definition that is contrary to the art accepted meaning of the term. The specification fails to provide guidance regarding additions or substitutions to the sequence of LAP or of deletions that do not result in contiguous fragments. However, based upon the paucity of guidance provided by the specification and the lack of predictability in the art regarding LAP derivatives, it would be impossible for the artisan to envision effective LAP-derived peptides other than the exemplified LAP polypeptide of SEQ ID NO: 1 or the C-terminal fragment of LAP disclosed as SEQ ID NO: 2. In addition, the specification fails to teach any proteins that are "homologs" of LAP. Support for a "fragment" of LAP is limited to the C-terminal fragment of LAP disclosed as SEQ ID NO: 2 because the specification fails to teach any other fragments of LAP that bind to an EP motif, including a failure to teach the minimal sequence of SEQ ID NO: 2 that binds to an EP motif.

In view of the nature of the invention, breadth of the claims, level of unpredictability in the art, quantity of experimentation necessary, limited working examples, and the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the

claimed invention and this is not sanctioned by the statute.

Claims 1-4 are included in this ground of rejection because they are LINKING CLAIMS that encompass the elected invention of claims 5 and 6.

5. Claims 1-4 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-4 broadly recite any "molecule" that binds to a target comprising an EP motif. However, the only "molecule" taught by the specification that binds to a target comprising an EP motif is LAP protein and certain fragments thereof. The specification does not describe any other type of molecule that binds to a target comprising an EP motif. Furthermore, the metes and bounds of the term "molecule" have not been clearly set forth in the present application, making it impossible to determine just which types of molecule are encompassed by the term.

Claim 1 merely describes the genus of claimed molecules in terms of function, i.e., by what they bind to rather than by what these molecules are in terms of structure. A definition by function does not suffice to define the genus because is only an indication of what the molecule does rather than what it is. See Vas-Cath v. Eli Lilly (43 USPQ2d 1398 at 1406).

Therefore, only the LAP protein and the fragments of LAP identified by SEQ ID NOs: 1 and 2 meet the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See Vas-Cath at page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see *Vas-Cath* at page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Iouzalen et al. (Eur. J. Immunol. [2001] 31:2885-2891; cited on form PTO-1449).

Iouzalen teaches a LAP protein comprising both SEQ ID NO: 1 [claim 5] and SEQ ID NO: 2 [claim 6]. The ability to bind to a target comprising an EP motif [claims 1-4] is an inherent property of the LAP protein. The prior art teaching anticipates the claimed invention.

This ground of rejection can be overcome by the submission of a certified copy of the EPO priority application in English.

7. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,919,616 to Aurelian et al. (A on form PTO-892).

The claims are broadly drawn to a molecule that binds to a target comprising an EP motif. The claims are drafted in such a manner that they are inclusive of any molecule that binds to any portion of the target, not just molecules that bind to the EP motif. The law of anticipation does not require that the reference "teach" what the subject patent teaches. Assuming that a reference is properly "prior art," it is only necessary that the claims under attack, as construed by the court, "read on" something disclosed in the reference, i.e., all limitations of the claim are found in the reference, or "fully met" by it (Kalman v. Kimberly-Clark Corporation, 218 USPQ 781 (Fed. Cir. 1983)).

The '616 patent teaches an HSV-2 peptide comprising two EP motifs (SEQ ID NO: 1, Abstract in particular). The '616 patent further teaches an antibody that binds to the peptide (column 1, lines 46-59 in particular). The prior art teaching anticipates the claimed invention.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
March 5, 2007

DAVID A. SAUNDERS
PRIMARY EXAMINER